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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,115	03/24/2004	Stefan Kappeler	KAPPELER=1B	4394
1444	7590	09/22/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			SLOBODYANSKY, ELIZABETH	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/807,115	Applicant(s) KAPPELER ET AL.	
	Examiner Elizabeth Slobodyansky, PhD	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a continuation of 09/985,936 now abandoned.

Claims 1-19 are pending.

Information Disclosure Statement

The information disclosure statement filed March 24, 2004 contains 2 pages of form PTO-892 from the parent application 09/985,936 that have been lined through. This fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, with dependent claims 2-9, 12-19, is drawn to a nucleic acid sequence coding for pre-prochymosin, prochymosin, or chymosin of a mammal of the suborder Tylopoda. Claims 2 and 19 limit mammal to the genus *Camelus*. Claims 3 and 6 limit mammal to *Camelus dromedaries*. Claim 10 recites "a different coding sequence" without describing the sequence.

Suborder of Tylopoda comprises various mammals. The genus of *Camelus* comprises various species including *Camelus dromedaries*. In a given species chymosin can be encoded by single or different genes.

Therefore, claims 1-10 and 12-19 are equivalent to claims that are drawn to genes and allelic variants of an undefined structure. Such variants encompass a great number of molecules having an unknown structure.

Thus, the claims are drawn to a large highly diverse genus of nucleic acid sequences from Tylopoda, *Camelus*, or *Camelus dromedaries* encoding pre-prochymosin, prochymosin, or chymosin.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials."

University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification the genus of said nucleic acid sequences is represented by a single plasmid pGAMpR-C containing *Camelus dromedaries* gene coding for chymosin (pages 18-19, Example 1). There is no description of variants that exist in any other *Camelus* genus or species. The general knowledge in the art does not provide any indication of how the structure of one allelic variant in one species is representative of unknown genes and alleles. The common attributes of the genus are not described.

Thus, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being nucleic acid sequence from Tylopoda, *Camelus*, or *Camelus dromedaries* encoding pre-prochymosin, prochymosin, or chymosin and fails to provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is

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insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence encoding chymosin contained in pGAMpR-C, does not reasonably provide enablement for a nucleic acid sequence from Tylopoda, *Camelus*, or *Camelus dromedaries* encoding pre-prochymosin, prochymosin, or chymosin having an unknown structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are broader than the enablement provided by the disclosure with regard to the huge number of all possible variant nucleic acid sequences.

The nature and breadth of the invention of claims 1-10 and 12-19 encompass any Tylopoda, *Camelus*, or *Camelus dromedaries* nucleic acid sequence encoding pre-prochymosin, prochymosin, or chymosin having an undefined structure.

While recombinant hybridization techniques are known, only highly homologous sequences can be identified using a given sequence. The state of the art provides no reasonable expectation of success in obtaining a nucleic acid sequence from Tylopoda, *Camelus*, or another gene of *Camelus dromedaries* and the result of such screening is unpredictable.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including nucleic acid sequences of any structure from Tylopoda, *Camelus*, or *Camelus dromedaries* encoding pre-prochymosin, prochymosin, or chymosin. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making a nucleic acid sequence from Tylopoda, *Camelus*, or *Camelus dromedaries* encoding pre-prochymosin, prochymosin, or chymosin is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The invention appears to employ novel vector pGAMpR-C and strains *Aspergillus niger var. awamori* CBS 108915 and CBS 108916. With regard to the vector that is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. Figure 3 represents the general composition of the vector not the exact sequences comprising thereof. The enablement requirements of 35 U.S.C. §112 may be satisfied by a deposit of the plasmids. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited *Aspergillus niger var. awamori* CBS 108915 and CBS 108916 on June 13, 2000 under the terms of the Budapest Treaty, (page 22, lines 22-25) but there is no indication in the specification as to public availability. An affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 would satisfy the deposit requirement made herein.

Conclusion

The post-filing art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kappeler et al (2006) Biochem. Biophys. Res. Comm., Vol. 342, No.2, pages 647-654) disclose vector pGAMpR-C and DNA encoding *Camelus dromedaries* chymosin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

September 18, 2006